REMARKS

Rejection of claims 1-17 and 19-37 under 35 U.S.C. § 102(b)

The Office Action maintained the rejection of claims 1-17 and 19-37 as anticipated by EP 0 521 562. For the following reasons, the applicant respectfully traverses.

The applicants previously argued that EP 0 521 562 was non-enabling for the presently claimed compositions because although the document in column 12, lines 55-56, mentions that the non-polar excipient(s) is to be removed, there is no teaching or even suggestion of how to do it. The Office Action stated at page 3 that this argument was unpersuasive:

> With regard to applicant's arguments that the reference does not teach how to remove the non-polar excipients, the examiner points out that as recognized by applicant himself the reference teaches the removal of the non-polar excipients and since this oil is volatile, the reference does not have to teach how to do it; it is within the skill of the art.

The applicants respectfully submit that the Office Action over-simplifies the situation. The issue is not merely whether it is within the ability of those of ordinary skill in the art to remove a volatile silicon oil. The issue is whether one skilled in the art could, without undue experimentaion, remove a non-polar vehicle from a a reversed vesicle system in a manner that yields at a powder whereby when the powder is dispersed in a biodegradable oil the percent yield of reversed vesicles is greater than when the same amount of reversed vesicles is prepared directly in the biodegradable oil.

Contrary to vesicular systems known at the time of filing the present application, the external phase consisted of a non-polar and not a polar vehicle. Conventional techniques for removing a polar vehicle from vesicular systems cannot be applied to reversed vesicular systems without further experimentation.

Furthermore, the ordinary artisan would not know what would happen to the physical structure of the reversed vesicles after removing the non-polar vehicle and would not know about the claimed properties of the residue after removing the non-polar phase. Without such knowledge, one could not know whether the method of removing the non-polar vehicle from the reversed vesicles would or did result in a powder with the presently claimed properties.

If the Office still contends that it was within the level os skill of the ordinary artisan to remove the non-polar vehicles of EP 0 521 562 to arrive at the presently claimed invention, the applicant respectfully request evidence of it. The applicant submits there is no such evidence.

In conclusion, therefore, because EP 0 521 562 is a non-enabling reference for the presently claimed powder composition, it cannot anticipate the present claims.

In addition, the applicant notes that in rejecting the claims as obvious, the Office Action statest at p. 4, at the end of the third paragraph, "What this reference lacks are the explicit teachings that the preparation is in the powder from [sic, form]." As the claims recite a powder, by the Office's own admission EP 0 521 562 cannot anticipate the present claims because it lacks a teaching of that claim element.

In view of the foregoing, therefore, reconsideration and withdrawal of this rejection is respectfully requested.

Rejection of claims 1-17 and 19-37 under 35 U.S.C. § 103

Claims 1-17 and 19-37 were rejected as obvious over EP 0 521 562 alone or in combination with EP 0 678 295, EP 0 159 237, GB 2002319, JP 051 94253 each alone or in combination. For the following reasons, the applicants respectfully traverse.

EP 0 521 562 relates - amongst other things - to stable dispersions of reversed vesicles in a biodegradable oil (glycerol tri-esters of higher saturated fatty acids having 10-30 carbon atoms, such as glyceryltrilaurate and hydrogenated castor oil, and vegetable oils, such as coconut oil and peanut oil). However, as noted above, EP 0 521 562 does not teach or suggest a method of making the instantly claimed powder of reversed vesicles.

The cited secondary references do not compensate for the deficiency of EP 0 521 562.

The Office alleges that

1. EP 0678 295 teaches that vesicular preparations (hydrophilic group of the lipid is oriented towards the continuous external phase (water) can be lyophilized to form powders (note example 1 and claims 1 and 7).
2. EP 0159237 teaches that emulsions (micelles) can be freeze-dried to form powders, which are easier to handle than emulsions (note the abstract).
3. GB 2002319 teaches that dehydration of lipid vesicles (liposomes) to prepare a stable powder, which can be stored for longer periods of time (note the abstract).
4. JP 05194253 teaches the preparation of a powder of reverse micelles containing a surfactant (note the abstract).

The applicant respectfully submits, however, that none of these references relate to the removal of a non-polar from a reversed vesicle and, therefore, one of ordinary skill in the art would not be motivated to combine the teachings of such art with the EP '562 patent publication. With regard to JP 05194253, the Office Action alleges that it teaches a power of reverse myself and point to the abstract for support. However, the abstract mentions nothing about a powder. Those skilled in the art recognize that methods used in other such systems are not directly applicable to reversed vesicular systems. The Office has not provided evidence to the contrary.

Nor does the art when combined provide a reasonable expectation of successfully obtaining a powder of reversed vesicles that, when dispersed in a biodegradable oil result in a percent yield of reversed vesicles that is greater than when the same amount of reversed vesicles is prepared directly in the biodegradable oil.

The present claims are not merely directed to a powder of reversed vesicles. Rather, they are directed to a powder of reverse vesicles that, when suspended in a biodegradable oil, yield a higher percentage of reversed vesicles then when the same amount of reversed vesicles is prepared directly in the biodegradable oil. None of the art recognize that such a powder could exist, and, therefore, the art cannot provide the requisite suggestion to make the presently claim powder. How can the art suggest the presently claimed powder of reversed vesicles if it did not recognize that such a powder having the recited properties could exist?

Similarly, the art could not provide one of ordinary skill in the art with a reasonable expectation of success in making the presently claimed powder with the recited property if the art did not recognize that such a powder could exist.

In summary, the primary reference fails to teach the presently claimed powder of reversed vesicles or the claimed method of making them, and the secondary art does not compensate for this deficiency because it addresses unrelated issues relating to different systems. Furthermore, the presently claimed invention possesses an unexpected property.

In view of the foregoing, therefore, the applicants respectfully request reconsideration and withdrawal of this § 103 rejection.

If there are any questions or comments regarding this Response or application, the Examiner is encouraged to contact the undersigned attorney as indicated below.

Respectfully submitted,

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